HFA-305

Date of Approval: JAN 22 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-347

Indications for use: Treatment of erysipelas in turkeys.

Sponsored by:
Phoenix Scientific, Inc.
St. Joseph, MO 64503

ANADA 200-347

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FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. ANADA Number	200-347
b. Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th St. Terrace St. Joseph, MO 64503 21 CFR 510.600: Labeler Code: 059130
c. Established Name:	Penicillin G Potassium USP Soluble Powder
d. Trade/Proprietary Name:	Penicillin G Potassium USP Soluble Powder
e. Dosage Form:	Soluble Powder for drinking water
f. How Supplied:	48 oz HDPE jugs
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each jug contains Penicillin G Potassium equivalent to 0.5 billion I.U.
i. Route of Administration:	Oral
j. Species:	Turkeys
k. Labeled Dosage and Administration:	Administer orally at a dosage of 1,500,000 units of penicillin per gallon (3.8L) of drinking water for 5 consecutive days.
l. Indications for Use:	Penicillin G Potassium Soluble Powder is indicated in turkeys for the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.

m. Pharmacological Category: Antibacterial

n. Pioneer Product: Penicillin G Potassium Soluble Powder manufactured by Fort Dodge Animal Health (NADA 55-060)

2. TARGET ANIMAL SAFETY and DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA Sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on July 3, 2001, from the requirement of an *in vivo* bioequivalence study for Penicillin G Potassium USP Soluble Powder. The generic and pioneer products contain the same active and inactive ingredients in nearly the same concentration as the pioneer and are oral solutions. The pioneer product, Penicillin G Potassium USP, the subject of Fort Dodge Animal Health's NADA 55-060 was approved on December 18, 1973.

3. HUMAN SAFETY:

Tolerance:

The tolerances established for the pioneer apply to the generic product.
Under section §556.510, Penicillin, a tolerance of 0.01 ppm is established for residues of penicillin in the uncooked edible tissues of turkeys.

Withdrawal Time:

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for Penicillin is established under 21 CFR 520.1696b. There is a one-day withdrawal period for turkeys.

Regulatory Methods for Residues:

The analytical method for the determination of penicillin in tissues uses a microbiological assay procedure using *Sarcina lutea*. This method is found in the Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Methods, Reports, and Protocols, revised October 1968, reprinted December 1974, National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204. The methods are on file at the Center for Veterinary Medicine, Food and Drug Administration, HFV-199, 7500 Standish Place, Rockville, Maryland 20855.

Human Safety Relative to Possession, Handling, and Administration:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Penicillin G Potassium Soluble Powder is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

ATTACHMENTS:

Pioneer Labeling for NADA 55-060:

48 ounce wide mouth jar labeling

Generic Labeling:

AmTech Penicillin G Potassium USP
48 ounce wide mouth jar labeling

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

r: 1 / op: hak / ldr: 12431A
06/20/98
code: FDL Size: $11^{7}/_{16}$" x $10^{3}/_{4}$"
Fort Dodge Penicillin G Potassium USP, pouch
file location: HD/proof folder/12431A/12431A

PMS 185
PMS 287

Warnings
Treated turkeys must not be slaughtered for food during treatment and for one day after last treatment.
Do not use in turkeys producing eggs for human consumption.

Precautions
For best results, the treatment should be started at the first sign of infection. If improvement is not noted after 3 to 4 days of treatment, consult a poultry pathologist or veterinarian.

Manufactured for
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
by G.C. Hanford Manufacturing Co.
Syracuse, NY 13201

92328
12431A

NDC 53501-059-02

Penicillin G Potassium USP

Antibiotic for drinking water

FORT DODGE®

For oral use in turkeys only
For veterinary use only
Store at room temperature; avoid excessive heat (104°F or 40°C).
Keep out of the reach of children
Restricted drug (under California law) – Use only as directed
Active Ingredient:
0.500 billion units penicillin G potassium
Nonsterile

NADA 55-060, Approved by FDA

Indications
For the treatment of erysipelas in turkeys (caused by *Erysipelothrix rhusiopathiae*).

Dosage and administration
Administer orally at a dosage of 1,500,000 units of penicillin per gallon (3.8 liters) of drinking water for 5 consecutive days.

Directions
Combine contents and approximately 1½ pints (710 mL) of water in a glass or plastic container. Stir to dissolve. Allow concentrated solution to stand until the foam disappears. The concentrated solution should be used up or discarded within one hour after preparation.

Automatic Watering Systems – Pour the concentrated solution into a glass or plastic container then add enough water to make 2.6 gallons (9.9 liters) of stock solution. [This amount of solution will medicate 333 gallons (1260 liters) of drinking water]. The automatic waterer should be adjusted to deliver 1 ounce (30 mL) of stock solution per gallon (3.8 liters) of drinking water. In automatic watering systems, prepare fresh solutions daily.

Gravity Flow Watering Systems – Pour the concentrated solution into enough water to make 333 gallons (1260 liters) of drinking water. In gravity flow watering systems, prepare fresh solutions every 12 hours.

Drinking water prepared as directed above will contain 1,500,000 units of penicillin G per gallon (3.8 liters).

DOSAGE AND ADMINISTRATION: Administer orally at a dosage of 1,500,000 units of penicillin per **gallon (3.8 liters)** of drinking water for 5 consecutive days.

DIRECTIONS: Add enough water **(approx. 2 pints - 946 mL)** to fill bottle two-thirds full. Shake to dissolve. Allow the concentrated solution to stand until foam disappears. The concentrated solution should be used up or discarded within one hour of preparation.

Automatic Watering Systems: Pour the concentrated solution into a glass or plastic container then add enough water to make **2.6 gallons (9.9 liters)** of stock solution. [This amount of solution will medicate **333 gallons (1260 liters)** of drinking water.] The automatic waterer should be adjusted to deliver **1 ounce (30 mL)** of stock solution per **gallon (3.8 liters)** of drinking water. Prepare fresh stock solutions and medicated drinking water solutions every twelve (12) hours. All solutions in contact with galvanized metal should be changed every three (3) hours.

Gravity Flow Watering Systems: Pour the concentrated solution into enough water to make **333 gallons (1260 liters)** of drinking water. In gravity flow watering systems, prepare fresh solution every 12 hours. All solutions in contact with galvanized metal should be changed every three (3) hours.

Drinking water prepared as directed above will contain 1,500,000 units of Penicillin G Potassium per **gallon (3.8 liters).**

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Lot No.

Exp. Date

NDC 59130-746-67

NET CONTENTS:
0.500 billion I.U.

PENICILLIN G POTASSIUM USP

Antibiotic for drinking water

For Oral Use in Turkeys Only

Active Ingredient: 0.500 billion units Penicillin G Potassium

Nonsterile

FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN

ANADA 200-347, Approved by FDA

AmTech® Group, Inc.

INDICATIONS: For treatment of erysipelas in turkeys caused by *Erysipelothrix rhusiopathiae.*

WARNINGS: Treated turkeys must not be slaughtered for food during treatment and for one day after last treatment.

Do not use in turkeys producing eggs for human consumption.

PRECAUTIONS: For best results, the treatment should be started at the first sign of infection. If improvement is not noted after 3 to 4 days of treatment, consult a poultry pathologist or veterinarian. Keep this and all medication out of reach of children. Restricted drug under California law. Use only as directed. Store at or below 25°C (77°F). Protect from excessive heat, 40°C (104°F), and moisture. Label recommendations for storage and replacement of stock and medicated water solution must be followed to assure the performance of this drug product.

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T-Iss. 8-01

TAKE TIME OBSERVE LABEL DIRECTIONS

Manufactured by
Phoenix Scientific, Inc.
Fort Dodge, IA 50501